

OCT 28 2003 16:07 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375#

P.03

**RECEIVED
CENTRAL FAX CENTER**

NOV 25 2003

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION****OFFICIAL**

INTERVENTIONAL THERAPIES, LLC

Plaintiff,

v.

GUIDANT CORPORATION,

Defendant.

No. CV02-2130

Judge Trimble

Mag. Judge Wilson

**DEFENDANT'S AMENDED ANSWER TO PLAINTIFF'S AMENDED
COMPLAINT, AMENDED COUNTERCLAIM AND JURY DEMAND**

Defendant Guidant Corporation ("Guidant"), by its attorneys, answers the Complaint of Plaintiff Interventional Therapies, LLC ("IT") as follows:

1. Guidant admits the allegations contained in paragraph 1 of the Complaint.
2. Guidant admits that IT purports to base its cause of action on the patent laws of the United States, 35 U.S.C. §§ 101 *et seq.*, but denies that IT has any cause of action.
3. Guidant admits that the Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), but denies that IT has any cause of action.
4. To the extent that personal jurisdiction over Guidant exists, Guidant admits that venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), but denies that this district is the most convenient or judicially efficient forum for this action.
5. Upon information and belief, IT is organized under the laws of Delaware and has a principal place of business at One Gorham Island, Westport, Connecticut 06880. Guidant is

OCT 28 2003 16:07 FR FINNEGAN HENDERSON 202 400 4400 TO 12128788375#

P.04

without knowledge or information sufficient to form a belief as to the remaining allegations contained in paragraph 5 of the Complaint and therefore denies them.

6. Guidant admits the allegations in paragraph 6 of the Complaint.

7. Guidant admits that it has a registered agent for service located at CT Corporation, 8550 United Plaza Boulevard, Baton Rouge, Louisiana. Guidant denies that it operates a regular place of business at the same address.

8. Guidant admits the allegations in paragraph 8 of the Complaint.

9. Guidant admits the allegations in paragraph 9 of the Complaint.

10. Guidant admits the allegations in paragraph 10 of the Complaint.

COUNT I

11. Answering paragraph 11 of the Complaint, Guidant refers to paragraphs 1 through 10 of this Answer as if fully set forth herein.

12. Guidant admits that U.S. Patent No. 5,503,614 ("the '614 patent"), entitled "Flexible Source Wire for Radiation Treatment of Diseases" issued on April 2, 1996, and lists Samuel F. Liprie as the inventor. Guidant denies that said patent was duly and legally issued.

13. Guidant admits that Exhibit A purports to be a copy of the '614 patent. Guidant denies that all rights, title, and interest in the '614 patent were properly assigned to IT

needs a period

14. Guidant admits that it is making, using, selling, and offering for sale the Galileo[®] Intravascular Radiotherapy System but denies that it has infringed, or continues to infringe, directly, contributorily, and/or through inducement, one or more claims of the '614 patent, and denies each and every one of the remaining allegations contained in paragraph 14 of the Complaint.

15. Guidant denies the allegations in paragraph 15 of the Complaint.

OCT 26 2003 16:07 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375H

P.05

16. Guidant denies the allegations in paragraph 16 of the Complaint.

17. Guidant denies the allegations in paragraph 17 of the Complaint.

COUNT II

18. Answering paragraph 18 of the Complaint, Guidant refers to paragraphs 1 through 17 of this Answer as if fully set forth herein.

19. Guidant admits that U.S. Patent No. 5,800,333 ("the '333 patent"), entitled "Afterloader Provided With Remote Control Unit" issued on September 1, 1998, and lists Samuel F. Liprie as inventor. Guidant denies that said patent was duly and legally issued.

20. Guidant admits that Exhibit B purports to be a copy of the '333 patent. Guidant denies that all rights, title, and interest in the '333 patent were properly assigned to IT.

21. Guidant admits that it is making, using, selling, and offering for sale the Galileo[®] Intravascular Radiotherapy System but denies that it has infringed, or continues to infringe, directly, contributorily, and/or through inducement, one or more claims of the '333 patent, and denies each and every one of the remaining allegations contained in paragraph 21 of the Complaint.

22. Guidant denies the allegations in paragraph 22 of the Complaint.

23. Guidant denies the allegations in paragraph 23 of the Complaint.

24. Guidant denies the allegations in paragraph 24 of the Complaint.

COUNT III

25. Answering paragraph 25 of the Complaint, Guidant refers to paragraphs 1 through 24 of this Answer as if fully set forth herein.

26. Guidant admits that U.S. Patent No. 5,857,956 ("the '956 patent"), entitled "Flexible Source Wire For Localized Internal Radiation of Tissue" issued on January 12, 1999,

OCT 28 2003 16:08 FR FINNEGAN HENDERSON 202 408 4400 TO 121287883754

P.06

and lists Samuel F. Liprie as the inventor. Guidant denies that said patent was duly and legally issued.

27. Guidant admits that Exhibit C purports to be a copy of the '956 patent. Guidant denies that all rights, title, and interest in the '956 patent were properly assigned to IT.

28. Guidant admits that it is making, using, selling, and offering for sale the Galileo® Intravascular Radiotherapy System but denies that it has infringed, or continues to infringe, directly, contributorily, and/or through inducement, one or more claims of the '956 patent, and denies each and every one of the remaining allegations contained in paragraph 28 of the Complaint.

29. Guidant denies the allegations in paragraph 29 of the Complaint.

30. Guidant denies the allegations in paragraph 30 of the Complaint.

31. Guidant denies the allegations in paragraph 31 of the Complaint.

COUNT IV

32. Answering paragraph 32 of the Complaint, Guidant refers to paragraphs 1 through 31 of this Answer as if fully set forth herein.

33. Guidant admits that U.S. Patent No. 6,505,392 ("the '392 patent"), entitled "Process for Manufacturing a Radioactive Source Wire for Irradiating Diseased Tissue" issued on January 14, 2003, and lists Samuel F. Liprie as the inventor. Guidant denies that said patent was duly and legally issued.

34. Guidant admits that Exhibit D purports to be a copy of the '392 patent. Guidant denies that all rights, title, and interest in the '392 patent were properly assigned to IT.

35. Guidant admits that it is making, using, selling, and offering for sale the Galileo® Intravascular Radiotherapy System but denies that it has infringed, or continues to infringe,

OCT 28 2003 16:08 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375#

P.07

directly, contributorily, and/or through inducement, one or more claims of the '392 patent, and denies each and every one of the remaining allegations contained in paragraph 35 of the Complaint.

36. Guidant denies the allegations in paragraph 36 of the Complaint.

37. Guidant denies the allegations in paragraph 37 of the Complaint.

38. Guidant denies the allegations in paragraph 38 of the Complaint.

AFFIRMATIVE DEFENSES

39. Guidant has not been and is not infringing, actively inducing others to infringe, or contributing to the infringement of the claims of the '614, '333, '956, and '392 patents.

40. By reason of the proceedings in the United States Patent and Trademark Office during prosecution of the applications that resulted in the issuance of the '614, '333, '956, and '392 patents, and related applications, including statements, arguments, amendments to the claims made during said prosecution by or on behalf of the patentee, IT is estopped to assert that Guidant has infringed or is infringing the '614, '333, '956, and '392 patents.

41. The '614, '333, '956, and '392 patents are invalid for failure to comply with the requirements of Part II of Title 35, United States Code, including, *inter alia*, the requirements of 35 U.S.C. §§ 102, 103, 112, and 116.

42. The '614 patent is unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including U.S. Patent No. 5,199,939; Application Serial No. 08/057,322; the prior manufacture, use, and sale of source wires made from Nitinol; the prior manufacture, use, and

OCT 28 2003 16:08 FR FINNEGAN HENDERSON 202 400 4400 TO 12128788375H

P.08

sale of source wires having a housing tube and backbone wire; U.S. Nuclear Regulatory Commission report dated February 1993 and entitled "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania, On November 16, 1992"; "Investigation of Failed Nitinol Brachytherapy Wire" by Southwest Research Institute dated August 1993; submissions to state and national nuclear regulatory commissions or radiation protection divisions describing Nitinol source wires and source wires having a housing tube and backbone wire, including a source wire having a Nitinol housing tube and Nitinol backbone wire; and the invention by others, including at least Anthony J. Bradshaw and John Edison, which, upon information and belief, the applicant for the '614 patent was aware of during the prosecution of the '614 patent and withheld with an intent to deceive.

43. The '333 patent is unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and afterloader technology, including the Mini-Loader Remote Afterloader; the prior invention by others, including at least Dr. Michael H. Hayman and Anthony Bradshaw; Application Serial No. 08/057,322; Samuel Liprie's admission that he is not an inventor of the subject matter disclosed in Application Serial No. 08/057,322; the prior manufacture, use, sale, and advertising of afterloaders, including by at least GammaMed, Nucletron, Omnitron, and Varian; U.S. Nuclear Regulatory Commission report dated February 1993 and entitled "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania, On November 16, 1992," which, upon information and belief, the applicant for the '333 patent was aware of during the prosecution of the '333 patent and withheld with an intent to deceive.

OCT 28 2003 16:08 FR FINNEGAN HENDERSON 202 408 4400 TO 12120788375#

P.09

44. The '956 patent, which issued from an application claiming priority to the '614 patent, is unenforceable based on the inequitable conduct involved in procuring the '614 patent. The '956 patent is also unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including Application Serial No. 08/057,322; Samuel Liprie's admission that he is not an inventor of the subject matter disclosed in Application Serial No. 08/057,322; the prior manufacture, use, and sale of source wires made from Nitinol; the prior manufacture, use, and sale of source wires having a housing tube and backbone wire; U.S. Nuclear Regulatory Commission report dated February 1993 and entitled "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania, On November 16, 1992"; "Investigation of Failed Nitinol Brachytherapy Wire" by Southwest Research Institute dated August 1993; submissions to state and federal nuclear regulatory commissions or radiation protection divisions describing Nitinol source wires and source wires having a housing tube and backbone wire, including a source wire having a Nitinol housing tube and Nitinol backbone wire; and the invention by others, including at least Anthony J. Bradshaw and John Edison, which, upon information and belief, the applicant for the '956 patent was aware of during the prosecution of the '956 patent and withheld with an intent to deceive.

45. The '392 patent, which issued from an application claiming priority to the '614 patent and the '956 patent, is unenforceable based on the inequitable conduct involved in procuring the '614 patent and the '956 patent. The '392 patent is also unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with

OCT 28 2003 16:09 FR FINNEGAN HENDERSON 202 400 4400 TO 12128788375#

P.10

the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including Samuel Liprie's admission that he is not an inventor of the subject matter disclosed in Application Serial No. 08/057,322; the prior manufacture, use, and sale of source wires made from Nitinol; the prior manufacture, use, and sale of source wires having a housing tube and backbone wire; U.S. Nuclear Regulatory Commission report dated February 1993 and entitled "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania. On November 16, 1992"; "Investigation of Failed Nitinol Brachytherapy Wire" by Southwest Research Institute dated August 1993; submissions to state and federal nuclear regulatory commissions or radiation protection divisions describing Nitinol source wires and source wires having a housing tube and backbone wire, including a source wire having a Nitinol housing tube and Nitinol backbone wire; and the invention by others, including at least Anthony J. Bradshaw and John Edison, which, upon information and belief, the applicant for the '392 patent was aware of during the prosecution of the '392 patent and withheld with an intent to deceive.

46. Recovery for any alleged infringement of the '614 patent is barred because IT does not have standing to sue for infringement as IT does not own exclusive rights to the '614 patent. The named inventor of the '614 patent, Samuel Liprie, was under an obligation to assign all right, title, and interest in such patent to Omnitron. In addition, at least Anthony J. Bradshaw and/or John Edison are a joint inventors of the '614 patent and were under an obligation to assign all right, title, and interest in such patent to Omnitron International, Inc. ("Omnitron"). Omnitron transferred all such right, title, and interest to Guidant, and IT does not have exclusive rights to the '614 patent.

OCT 28 2003 16:09 FR FINNEGAN HENDERSON 202 400 4400 TO 12128788375#

P. 11

47. Recovery for any alleged infringement of the '333 patent is barred because IT does not have standing to sue for infringement as IT does not own exclusive rights to the '333 patent. All title, right, and interest in the '333 patent is lawfully in Guidant. The named inventor of the '333 patent, Samuel Liprie, was under an obligation to assign all right, title, and interest in such patent to Omnitron. In addition, at least Dr. Michael H. Hayman and/or Anthony J. Bradshaw are joint inventors of the '333 patent and were under an obligation to assign all right, title, and interest in such patent to Omnitron. Omnitron transferred all such right, title, and interest to Guidant. IT therefore did not acquire any ownership rights in the '333 patent.

48. Recovery for any alleged infringement of the '956 patent is barred because IT does not have standing to sue for infringement as IT does not own exclusive rights to the '956 patent. All title, right, and interest in the '956 patent is lawfully in Guidant. The named inventor of the '956 patent, Samuel Liprie, was under an obligation to assign all right, title, and interest in such patent to Omnitron. In addition, at least Anthony J. Bradshaw and/or John Edison are joint inventors of the '956 patent and were under an obligation to assign all right, title, and interest in such patent to Omnitron. Omnitron transferred all such right, title, and interest to Guidant. IT therefore did not acquire any ownership rights in the '956 patent.

49. Recovery for any alleged infringement of the '392 patent is barred because IT does not have standing to sue for infringement as IT does not own exclusive rights to the '392 patent. All title, right, and interest in the '392 patent is lawfully in Guidant. The named inventor of the '392 patent, Samuel Liprie, was under an obligation to assign all right, title, and interest in such patent to Omnitron. In addition, at least Anthony J. Bradshaw and/or John Edison are joint inventors of the '392 patent and were under an obligation to assign all right, title, and interest in

OCT 28 2003 16:09 FR FINNEGAN HENDERSON 202 408 4400 TO 12128708375H

P.12

such patent to Omnitron. Omnitron transferred all such right, title, and interest to Guidant. IT therefore did not acquire any ownership rights in the '392 patent.

50. Recovery for any alleged infringement of the '614, '333, '956, or '392 patent is barred by laches and equitable estoppel.

COUNTERCLAIMS

By way of its counterclaims against IT, Guidant alleges as follows:

51. Guidant repeats and realleges, and incorporates herein by reference, each of the allegations set forth in paragraphs 1 through 50 above.

52. These Counterclaims arise under the Federal Declaratory Judgment Act and the Patent Laws of the United States, and more particularly, under Title 28 U.S.C. §§ 2201 and 2202, and Title 35 U.S.C. §§ 101, *et seq.*, respectively. Jurisdiction is based on Title 28 U.S.C. §§ 1338 and 2201.

53. Venue in this district is proper pursuant to 28 U.S.C. § 1391 and because IT has subjected itself to the jurisdiction of this Court by filing its Complaint in this district.

54. IT alleges that it is a Delaware corporation having its principal place of business at One Gorham Island, Westport, Connecticut 06880, and maintains a place of business located at 960 West Lincoln Road, Lake Charles, Louisiana 70605.

55. Guidant is an Indiana corporation having its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana 46204.

56. There is an actual case or controversy between Guidant and IT because IT has charged Guidant with infringement of U.S. Patent Nos. 5,503,614; 5,800,333; 5,857,956; and 6,505,392 and has filed this suit against Guidant in this Court for the alleged infringement.

OCT 28 2003 16:10 FR FINNEGAN HENDERSON 202 400 4400 TO 12128780375#

P.13

57. The '614 patent is invalid. The '614 patent is also unenforceable for inequitable conduct. Guidant has not and is not infringing, actively inducing the infringement of, or contributing to the infringement of any claim of the '614 patent.

58. At least Anthony J. Bradshaw and John Edison are joint inventors of the '614 patent. Anthony J. Bradshaw and John Edison were not named as inventors of the '614 patent without deceptive intent on their part. Guidant owns Anthony J. Bradshaw's and John Edison's interest in the '614 patent and seeks correction of inventorship under 35 U.S.C. § 256 and a declaration that Guidant is an owner of the '614 patent.

59. Guidant is the owner of the '614 patent by way of Samuel Liprie's obligation to assign all right, title, and interest in the '614 patent to Omnitron

60. The '333 patent is invalid. The '333 patent is also unenforceable for inequitable conduct. Guidant has not and is not infringing, actively inducing the infringement of, or contributing to the infringement of any claim of the '333 patent.

61. At least Dr. Michael H. Hayman and Anthony J. Bradshaw are joint inventors of the '333 patent. Dr. Michael H. Hayman and Anthony J. Bradshaw were not named as inventors of the '333 patent without deceptive intent on their part. Guidant owns Dr. Michael H. Hayman's and Anthony J. Bradshaw's interest in the '333 patent and seeks correction of inventorship under 35 U.S.C. § 256 and a declaration that Guidant is an owner of the '333 patent.

62. Guidant is the owner of the '333 patent by way of Samuel Liprie's obligation to assign all right, title, and interest in the '333 patent to Omnitron.

63. The '956 patent is invalid. The '956 patent is also unenforceable for inequitable conduct. Guidant has not and is not infringing, actively inducing the infringement of, or contributing to the infringement of any claim of the '956 patent.

OCT 28 2003 15:10 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375H

P.14

64. At least Anthony J. Bradshaw and John Edison are joint inventors of the '956 patent. Anthony J. Bradshaw and John Edison were not named as inventors of the '956 patent without deceptive intent on their part. Guidant owns Anthony J. Bradshaw's and John Edison's interest in the '956 patent and seeks correction of inventorship under 35 U.S.C. § 256 and a declaration that Guidant is an owner of the '956 patent.

65. Guidant is the owner of the '956 patent by way of Samuel Liprie's obligation to assign all right, title, and interest in the '956 patent to Omnitron.

66. The '392 patent is invalid. The '392 patent is also unenforceable for inequitable conduct. Guidant has not and is not infringing, actively inducing the infringement of, or contributing to the infringement of any claim of the '392 patent.

67. At least Anthony J. Bradshaw and John Edison are joint inventors of the '392 patent. Anthony J. Bradshaw and John Edison were not named as inventors of the '392 patent without deceptive intent on their part. Guidant owns Anthony J. Bradshaw's and John Edison's interest in the '392 patent and seeks correction of inventorship under 35 U.S.C. § 256 and a declaration that Guidant is an owner of the '392 patent.

68. Guidant is the owner of the '392 patent by way of Samuel Liprie's obligation to assign all right, title, and interest in the '392 patent to Omnitron.

69. For having brought this action, IT is liable under 35 U.S.C. § 285, and Guidant seeks recovery from IT pursuant to that statute as part of this Counterclaim.

PRAYER

WHEREFORE, Guidant denies that IT is entitled to any of the relief prayed for in the Complaint, and Guidant prays that judgment be entered against IT as follows:

A. Dismiss the Complaint with prejudice;

OCT 28 2003 16:10 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375#

P.15

B. Declare the '614 patent invalid;

C. Declare the '614 patent unenforceable;

D. Declare the '614 patent not infringed by Guidant;

E. Declare that Anthony J. Bradshaw and John Edison are joint inventors of the '614 patent, and issue an order pursuant 35 U.S.C. § 256 directing the Director of the United States Patent & Trademark Office to correct inventorship of the '614 patent to include at least Anthony J. Bradshaw and John Edison;

F. Declare that Guidant is an owner and the exclusive owner of the '614 patent and any related applications or subsequent patents issuing there from and that all assignments to anyone else are null and void;

G. Declare the '333 patent invalid;

H. Declare the '333 patent unenforceable;

I. Declare the '333 patent not infringed by Guidant;

J. Declare that Dr. Michael H. Hayman and Anthony J. Bradshaw are joint inventors of the '333 patent and issue an order pursuant 35 U.S.C. § 256 directing the Director of the United States Patent & Trademark Office to correct inventorship of the '333 patent to include at least Dr. Michael H. Hayman and Anthony J. Bradshaw;

K. Declare that Guidant is an owner and the exclusive owner of the '333 patent and any related applications or subsequent patents issuing therefrom and that all assignments to anyone else are null and void;

L. Declare the '956 patent invalid;

M. Declare the '956 patent unenforceable;

N. Declare the '956 patent not infringed by Guidant;

OCT 28 2003 16:11 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375H

P. 16

O. Declare that Anthony J. Bradshaw and John Edison are joint inventors of the '956 patent and issue an order pursuant 35 U.S.C. § 256 directing the Director of the United States Patent & Trademark Office to correct inventorship of the '956 patent to include at least Anthony J. Bradshaw and John Edison;

P. Declare that Guidant is an owner and the exclusive owner of the '956 patent and any related applications or subsequent patents issuing therefrom and that all assignments to anyone else are null and void;

Q. Declare the '392 patent invalid;

R. Declare the '392 patent unenforceable;

S. Declare the '392 patent not infringed by Guidant;

T. Declare that Anthony J. Bradshaw and John Edison are joint inventors of the '392 patent and issue an order pursuant 35 U.S.C. § 256 directing the Director of the United States Patent & Trademark Office to correct inventorship of the '392 patent to include at least Anthony J. Bradshaw and John Edison;

U. Declare that Guidant is an owner and the exclusive owner of the '392 patent and any related applications or subsequent patents issuing therefrom and that all assignments to anyone else are null and void.

V. Declare this case exceptional under 35 U.S.C. § 285 and award Guidant its reasonable attorney fees and expenses of litigation;

W. Award Guidant costs of this suit; and

X. Award such other relief as this Court deems just and proper.

OCT 28 2003 16:11 FR FINNEGAN HENDERSON 202 408 4400 TO 12128788375H

P.17

DEMAND FOR JURY TRIAL

Guidant hereby demands trial by jury of all issues so triable in this action.

Dated: October 30, 2003

Respectfully submitted,

J. Michael Veron (La Bar No. 7570)
SCOFIELD, GERARD, VERON,
SINGLETTARY & POHORLESKY, PLC
1114 Ryan Street
Lake Charles, LA 70601
(337) 433-9436

J. Michael Jakes
Kathleen A. Daley
Troy E. Grabow
Edward J. Naidich
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005
(202) 408-4000

Attorneys for Defendant
GUIDANT CORPORATION